



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/367,459	05/08/2000	Artur Mitterer	BHV-305.01	4372

7590 02/21/2003

Townsend and Townsend and Crew LLP
Two E mbarcadero center 8th floor
San Francisco, CA 94111-3834

EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
----------	--------------

1653

19

DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/367,459

Applicant(s)
Mitterer et al.

Examiner
HOPE ROBINSON

Art Unit
1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 8, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-39 is/are pending in the application.
- 4a) Of the above, claim(s) 26-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-25, 38, and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. PCT/AT98/00043.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 16 6) ☐ Other:

Art Unit: 1653

DETAILED ACTION

1. Applicant's response to the Office Action mailed May 8, 2002 in Paper No. 18 on November 8, 2002 is acknowledged.
2. Claims 17-21 and 25 have been amended. Claims 38-39 have been added. Claims 17-39 are pending. Claims 17-25 and 38-39 are under examination.
3. The following grounds of rejection are or remain applicable :

Abstract

4. The abstract is objected to because Amendment B filed November 8, 2002 does not contain an abstract of the disclosure as required by 37 CFR 1.72(b) on a separate sheet of paper.

An abstract on a separate sheet is required.

Information Disclosure Statement

5. The information disclosure statements filed on May 8, 2000 and November 8, 2002 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP 609 because there are items listed

Art Unit: 1653

on the information disclosure statement are not translated or are missing from the application. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. A line has been drawn through the following items on the information disclosure statement: AI, AK, AL, AM, AN and AO filed May 8, 2000 and through items AB, AC and AD on the one filed November 8, 2002 as the translations were not found in the application.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 18 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is indefinite for the recitation of "...wherein said factor VIII/vWF-complex is bound to said cation exchanger at a salt concentration of $\leq 250\text{mM}$ and factor VIII/vWF-complex containing low molecular weight vWF multimers, factor VIII free from platelet agglutinating vWF activity, and factor VIII:C is eluted and recovered...." because it is unclear what components are bound together and which are eluted. It appears that words are missing from the claims. For example, "...wherein said factor VIII/vWF-complex is bound to said cation

Art Unit: 1653

exchanger at a salt concentration of $\leq 250\text{mM}$ and a factor VIII/vWF-complex containing low molecular weight vWF multimers, a factor VIII free from platelet agglutinating vWF activity, and a factor VIII:C, wherein the factor VIII/vWF-complex is eluted and recovered....". Note that because the starting material in independent claim 17 is a "factor VIII/von Willebrand factor complex" and the end product appears to be "factor VIII:C" as recited in dependent claim 18, the claim lacks antecedent basis.

Claim 21 is indefinite for the recitation of "substantially free" because it is unclear how much is considered to be substantial.

Basis For NonStatutory Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 1653

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 17-25 and 38-39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-40 of U.S. Patent No. 6,465,624. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are directed to a method of recovering vWF/factor VIII/vWF complex. The patented claims recites a method of recovering vWF comprising a low salt concentration and binding vWF to a cation exchanger. The method also involves elution and recovery of purified vWF. The present application recites a method of recovering factor VII/vWF-complex by using a cation exchanger and a step wise elution process. Both the instant application and patent disclose similar method steps although the scope of the claims are different. Therefore, the disclosure in the patent makes obvious the claimed invention in the instant application. Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions since the

Art Unit: 1653

language in the claim is similar. Thus, the instant application claim is an obvious variation of the patented claim.

9. Applicant's amendment filed November 8, 2002 has been considered. Note that rejections under 35 U.S.C. 112, second paragraph and 103, Obvious Type Double Patenting remains. Regarding the rejections under 35 U.S.C. 112, second paragraph, note that new grounds of rejections have been instituted for the reasons stated above. The response on page 6 states that applicant request that the provisional double patenting rejection be held in abeyance until notification of allowable subject matter. Note that the rejection has changed because the copending application is now U.S. Patent No.6,465,624. As a terminal disclaimer was not filed the rejection remains.

Art of Record

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following reference not relied upon appear to be pertinent to the claimed invention, however, applicant has not provided a translation (see the objection to the IDS above), AE (WO97/39033). It is noted that applicant's response indicated the submission of English translations of three documents, however, the translations are missing from the application. It is suggested that they be resubmitted.

Art Unit: 1653

Conclusion


11. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 5:30 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope A. Robinson, MS 

Patent Examiner


KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER